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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,143	08/25/2000	Kevin D.J. Bowden	SW7255US	5341

22203 7590 10/22/2003
MARK KUSNER COMPANY LPA
HIGHLAND PLACE SUITE 310
6151 WILSON MILLS ROAD
HIGHLAND HEIGHTS, OH 44143

EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/22/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,143

Applicant(s)

BOWDEN, KEVIN D.J.

Examiner

Mital B. Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 23 July 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment/Arguments

1. Applicant's arguments filed 7/23/03 have been fully considered but they are not persuasive.
2. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

3. Claim 13 is objected to because of the following informalities: Claim 13 is dependent on canceled claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cross (US 2,990,838) in view of Bauman (US 5,537,998).
6. **As to claim 1**, Cross teaches a manually operated resuscitation device comprising a patient interface **14** having a gas inlet **12c** and gas outlet adapted to deliver gas to a patient airway; a flow control valve **16** disposed in flow communication between the gas inlet and a source of pressurized gas, the flow control valve being

operable between a minimum gas flow rate and a maximum gas flow rate, the flow control valve comprising a valve seat **18** and a valve plug (**See Figs 1, 7, and 8**) defining a flow control orifice **26** there between, wherein the plug includes a gas flow impingement surface and a valve seat mating surface, the plug being normally biased away from the valve seat and urged toward the valve seat by gas flow impinging against the gas flow impingement surface. Cross fails to specifically teach the interface having a one way intake valve downstream of the gas inlet. However, Bauman does teach a one-way intake valve to allow for air to only flow in one direction away from the source of pressurized gas. Therefore, it would have been obvious to one of ordinary skill in the art to provide a one-way intake valve in the device of Cross to allow for air to only flow in one direction away from the source of pressurized gas.

7. **As to claim 2**, the above combination teaches a device wherein the patient interface is selected from the group consisting of a bag-valve mask device; a pocket mask device wherein the patient interface comprises a patient mask **14** with the gas inlet and a patient face sealing edge; an endotracheal tube; and a face shield device comprising a flexible sheet with a tube therethrough, the tube having an upper end with operator mouthpiece about the gas inlet and a lower end with patient mouthpiece.

8. **As to claim 8**, the above combination teaches a device wherein the housing includes a bulkhead downstream of the valve seat, the bulkhead including at least one perforation **16g**; and wherein the plug is mounted to an upstream end of a valve stem **36**, the valve stem is slidably mounted within a through bore in the bulkhead with a spring **20** disposed about the valve stem between the plug and the bulkhead.

9. **As to claim 9**, the above combination teaches a device wherein the valve stem includes a retainer means **22,38** of the bulkhead.
10. **As to claim 10**, the above combination teaches a device wherein the retainer comprises a shoulder with the bulkhead abutting surface.
11. **As to claim 11**, the above combination teaches a device wherein the valve stem includes a motion limiter disposed on the valve stem a selected distance from the bulkhead (**See Figs. 1,7,8**).
12. **As to claim 12**, the above combination teaches a device wherein the motion limiter comprises a shoulder with the bulkhead abutting surface.
13. **As to claim 13**, the above combination teaches a device wherein the valve seat and valve seat mating surface are conical surfaces.
14. **As to claim 14**, the above combination teaches a device wherein the valve stem and bulkhead bore have a clearance space disposed therebetween sufficient to allow lateral motion of the valve plug relative to the valve seat.
15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cross (US 2,990,838) in view of Bauman (US 5,537,998) and further in view of Ruben (US 3,009,459).
16. **As to claim 3**, Cross teaches essentially all of the limitations except a bag-valve-mask device with a flexible bag having a one way intake valve and an exhaust port means. However, Cross does disclose that the face mask may be replaced with any other resuscitator type device as suited for human resuscitation. Therefore, it would be obvious to one of ordinary skill in the art to substitute the mask of Cross with a bag-

valve-mask device since Cross has disclosed such a substitution as a mechanical expedient. Furthermore, the above combination fails to specifically teach a one-way output valve in the flexible bag. However, Ruben does teach the use of a one-way output valve in order to prevent expansion of the bag from creating negative pressure at the gas inlet and ensuring that the bag is inflated through the input one way valve. Therefore, it would be obvious to one of ordinary skill in the art to provide a one-way output valve as taught by Ruben in order to prevent expansion of the bag from creating negative pressure at the gas inlet and ensuring that the bag is inflated through the input one way valve.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6622743, US 6516800, US 6102038, US 5687709, US4836198, US 4774941, US 4622964, US 4239038, US 4004603, US 3964476, and US 3672366.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

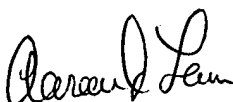
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Aaron J. Lewis
Primary Examiner

mbp